

## **REMARKS**

### **I. Introduction**

Claims 15 to 32 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

Applicant thanks the Examiner for considering the previously filed Information Disclosure Statement, PTO-1449 paper and cited references.

### **II. Amendments to the Specification**

The Specification has been amended herein without prejudice to delete “ab” between “ultra-filtrate line 20” and “which” in the paragraph beginning at page 6, line 1. No new matter has been added.

### **III. Rejection of Claims 15, 20, 22, 24, 29 and 31 Under 35 U.S.C. § 102(b)**

Claims 15, 20, 22, 24, 29 and 31 were rejected under 35 U.S.C. § 102(b) as anticipated by European Patent Application No. EP0911044 A1 (“Spickermann”). It is respectfully submitted that Spickermann does not anticipate these claims for at least the following reasons.

It is “well settled that the burden of establishing a prima facie case of anticipation resides with the [United States] Patent and Trademark Office.” *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1788 to 1789 (Bd. Pat. App. & Inter. 1986). To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

Claim 15 relates to a method for the determination of a blood volume during an extracorporeal blood treatment with a blood treatment apparatus in an extracorporeal blood circuit. As amended herein without prejudice, claim 15 recites the step of generating pulse waves that originate in the extracorporeal blood circuit, wherein the pulse waves have at least one of a propagation rate and a transit time. Support for this amendment may be found, for example, at page 4, lines 3 to 6 of the Specification. Claim 15 further recites the

step of *determining the blood volume from the at least one of the measured propagation rate and the measured transit time of the pulse waves.*

Claim 24 relates to a device for the determination of the blood volume during an extracorporeal blood treatment in an extracorporeal blood circuit. As amended herein without prejudice, claim 24 recites a means for generating pulse waves that originate in the extracorporeal blood circuit, wherein the pulse waves have at least one of a propagation rate and a transit time. Support for this amendment may be found, for example, at page 4, lines 3 to 6 of the Specification. Claim 24, as amended herein without prejudice, further recites an *an analyzing unit configured to determine the blood volume from the at least one of the measured propagation rate and the measured transit time of the pulse waves.* Support for this amendment may be found, for example, at page 7, lines 14 to 16 of the Specification. Claims 29 to 32 have been amended herein without prejudice to accord with amended claim 24. No new matter has been added.

Spickermann relates to a procedure for the continuous monitoring of an extracorporeal blood treatment. As an initial matter, Spickermann does not disclose or suggest generating pulse waves that originate in the extracorporeal blood circuit or a means thereof. Notwithstanding the foregoing, Spickermann does not disclose, or even suggest, determining a blood volume. In this regard, Spickermann discloses determining blood pressure  $P$  based on the pulse wave transit time  $PWLZ$  using equation (3), where  $m$  and  $n$  are determined by comparative measurements with a conventional blood pressure apparatus. See, e.g., paragraph 0028. The only necessary variables for determining pressure  $P$  according to equation (3) are the pulse wave transit time  $PWLZ$ ,  $m$ , and  $n$ . Alternatively, the blood pressure could be determined from the pulse wave velocity  $PWG$ , along with patient specific variables  $a$  and  $b$ , according to equation (2). *Id.* While equation (1) lists a volume variable  $V$ , a volume determination cannot be made without further information, e.g., blood density  $\rho$  and the change in blood pressure over the change in blood volume  $dP/dV$ . Spickermann recites equation (1) to demonstrate a general relationship between the pulse wave velocity  $PWG$  and the blood pressure, while equations (2) and (3) are used to determine the blood pressure based on the pulse wave velocity  $PWG$  and the pulse wave transit time  $PWLZ$ . See *id.* It is thus clear that Spickermann does not disclose or suggest a step of determining the blood volume from at least one of the measured propagation rate and the measured transit time of the pulse waves or an analyzing unit configured to determine the blood volume from at least one of the measured propagation rate and the measured transit time of the pulse waves.

As for claims 16, 17, 19 to 23, 25, 26 and 28 to 32, which ultimately depend from either claim 15 or claim 24, it is respectfully submitted that Spickermann does not anticipate these dependent claims for at least the same reasons more fully set forth above in support of the patentability of claims 15 and 24.

In view of all of the foregoing, withdrawal of this rejection is respectfully requested.

**IV. Rejection of Claims 15 to 17, 25 and 26 Under 35 U.S.C. § 103(a)**

Claims 15 to 17, 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Spickermann and U.S. Patent No. 6,623,443 (“Polaschegg”). It is respectfully submitted that the combination of Spickermann and Polaschegg does not render unpatentable these claims for at least the following reasons.

As indicated above, Spickermann does not disclose or suggest a step of determining a blood volume from at least one of the measured propagation rate and the measured transit time of the pulse waves or an analyzing unit configured to determine the blood volume from at least one of the measured propagation rate and the measured transit time of the pulse waves, as recited in claims 15 and 24, respectively. Polaschegg, relating to a method and device for the detection of stenosis in extracorporeal blood treatment, also fails to disclose, or even suggest, these features.

As indicated above, the combination of Spickermann and Polaschegg does not disclose, or even suggest, all of the features recited in either of claims 15 and 24. It is therefore respectfully submitted that the combination of Spickermann and Polaschegg does not render unpatentable any of claims 15 and 24.

Claims 16 and 17 ultimately depend from claim 15 and therefore include all of the features recited in claim 15. It is therefore respectfully submitted that the combination of Spickermann and Polaschegg does not render unpatentable any of claims 16 and 17 for at least the same reasons set forth above in support of the patentability of claim 15.

Claims 25 and 26 ultimately depend from claim 24 and therefore include all of the features recited in claim 24. It is therefore respectfully submitted that the combination of Spickermann and Polaschegg does not render unpatentable any of claims 25 and 26 for at least the same reasons set forth above in support of the patentability of claim 24.

In view of all of the foregoing, withdrawal of this rejection is respectfully requested.

**V. Rejection of Claims 18, 19, 21, 23, 27, 28, 30 and 32 Under 35 U.S.C. § 103(a)**

Claims 18, 19, 21, 23, 27, 28, 30 and 32 were rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Spickermann, Polaschegg, and U.S. Patent No. 5,293,874 (“Takahashi et al.”). It is respectfully submitted that the combination of Spickermann, Polaschegg, and Takahashi et al. does not render unpatentable these claims for at least the following reasons.

Claims 18, 19, 21 and 23 ultimately depend from claim 15 and therefore include all of the features recited in claim 15. As more fully set forth above, the combination of Spickermann and Polaschegg does not disclose, or even suggest, all of the features recited in claim 15. Takahashi et al. are not relied upon for disclosing or suggesting the features of claim 15 not disclosed or suggested by the combination of Spickermann and Polaschegg. Indeed, Takahashi et al. do not disclose, or even suggest, the features of claim 15 not disclosed or suggested by the combination of Spickermann and Polaschegg.

Claims 27, 28, 30 and 32 ultimately depend from claim 24 and therefore include all of the features recited in claim 24. As more fully set forth above, the combination of Spickermann and Polaschegg does not disclose, or even suggest, all of the features recited in claim 24. Takahashi et al. are not relied upon for disclosing or suggesting the features of claim 24 not disclosed or suggested by the combination of Spickermann and Polaschegg. Indeed, Takahashi et al. do not disclose, or even suggest, the features of claim 24 not disclosed or suggested by the combination of Spickermann and Polaschegg.


In view of all of the foregoing, it is respectfully submitted that the combination of Spickermann, Polaschegg, and Takahashi et al. does not disclose, or even suggest, all of the features of the present claims. As such, it is respectfully submitted that the combination of Spickermann, Polaschegg, and Takahashi et al. does not render unpatentable the present claims. Accordingly, withdrawal of the present rejection is respectfully requested.

**VI. Conclusion**

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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